TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN 10/14/96 AND 10/25/96—Continued

Acquiring person/acquired person/acquired entity	PMN No.	Date terminated
Alliance Phamaceutical Corp. Henry L. Hillman, MDV Technologies, Inc	97–0179	10/25/96
Rush Presbyterian—St. Luke's Medical Center, Riverside Health System, Riverside Health System	97–0187	10/25/96
The Beacon Group III—Focus Value Fund, L.P., Berwind Group Partners, Micorpore Inc	97–0188	10/25/96
Aker ASA, Kjell Inge Rokke, RGI (Norway) AS	97–0189	10/25/96

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Parcellena P. Fielding, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room 303, Washington, D.C. 20580, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 96–29024 Filed 11–15–96; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0308]

Countrymark Cooperative, Inc.; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Countrymark Cooperative, Inc. The NADA provides for the use of tylosin Type A medicated articles to make Type C medicated feeds. Countrymark Cooperative requested the withdrawal of approval of the NADA because they are no longer making Type A medicated articles for use in Type C medicated feeds. In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the regulations by removing those entries which reflect approval of the NADA.

EFFECTIVE DATE: November 29, 1996.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION: Countrymark Cooperative, Inc., 950 North Meridian St., Indianapolis, IN 46204–3909 (formerly the Indiana Farm Bureau Cooperative Association, Inc., 120 East Market St., Indianapolis, IN 46204), has voluntarily requested withdrawal of approval of NADA 125–226 that provides for use of tylosin Type A medicated articles to make tylosin Type C medicated swine feeds.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 125–226, and all supplements and amendments thereto is hereby withdrawn, effective November 29, 1996.

In a final rule published elsewhere in this issue of the Federal Register, FDA is amending 21 CFR 510.600 and 558.625 to reflect withdrawal of approval of this NADA.

Dated: October 18, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–29390 Filed 11–15–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0425]

Paclitaxel Drug Products; Environmental Information Needed in New Drug Applications, Abbreviated New Drug Applications, and Investigational New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this document to clarify the environmental information that must be submitted to the Center for Drug Evaluation and Research (CDER) for drug products containing paclitaxel. Paclitaxel is an active moiety that may be obtained or derived from various wild or cultivated species of yews. Under the National Environmental Policy Act (NEPA), all Federal agencies are required to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. This action is being taken to ensure that environmental factors regarding paclitaxel drug products are adequately assessed.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5721.

SUPPLEMENTARY INFORMATION:

I. Background

NEPA requires all Federal agencies to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. FDA is required under NEPA to consider the environmental impacts of approving drug product applications as an integral part of its regulatory process. FDA's regulations in 21 CFR part 25 specify that environmental assessments (EA's) or abbreviated environmental assessments (AEA's) must be submitted as part of NDA's, antibiotic drug applications, ANDA's, AADA's, IND's, and for other various actions described under § 25.22, unless the action qualifies for a categorical exclusion under §§ 25.23 and 25.24. FDA's regulations at § 25.23(c) provide that a person submitting an application for an action that falls within a class that qualifies for a categorical exclusion shall specify the provision that excludes the action from the requirement for an EA. FDA may require an applicant to provide information that establishes to the agency's satisfaction that the action requested is included within an excluded category and meets the criteria for the applicable exclusion (§ 25.23(c)). FDA will require an EA for any specific action that ordinarily is excluded if the agency has sufficient evidence to establish that the specific proposed action may significantly affect the quality of the human environment (§ 25.23(b)). In the Federal Register of January 11, 1996 (61 FR 1031), FDA announced the availability of a CDER guidance document entitled ''Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements'' (Guidance for Industry). The document was intended to provide guidance on how to prepare EA's for submission to